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10/531,476

04/15/2005

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EXAMINER

TOTH, KAREN E

ART UNIT

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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/531,476 | Applicant(s) MADAUS ET AL. | |
| | Examiner KAREN E. TOTH | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21, 22 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 19, 20 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/15/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. The claims generally appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Many of the claims, including but not limited to claims 2, 5, 6, 8, 11, 12, 17, 19, 21, 22, and 23, call for performing steps in addition to the method steps set forth in claim 1; it is suggested that they be amended in part to read --further comprising [new limitation]--, or similar.

Claims 3, 6, and 7 require performing measurement of inspiration and expiration times to perform the claimed steps. There is insufficient antecedent basis for this limitation in the claims. It is suggested that the claims be amended to depend from claim 2, which performs this step.

Claim 9 recites the limitation "consideration of the differential" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 13 and 14 recite the limitation "the trend analysis is effected" in line 2. There is insufficient antecedent basis for this limitation in the claims.

Claim 17 recites the limitation "the evaluation procedure is carried out" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 appears to further describe the differential calculated in claim 15; for the purposes of examination, it will be treated as though depending from claim 15.

Claims 18 and 23 appears to further describe the evaluation performed in claim 17; for the purposes of examination, they will be treated as though depending from claim 17.

Claim 22 appears to further describe the analysis performed in claim 21; for the purposes of examination, it will be treated as though depending from claim 21.

Claim 26 includes limitations for both a breathing mask and a breathing mask device; if these are intended to be a single component, it is suggested that the claim be amended to read --it includes a breathing mask device, and a respiratory gas line extending between the delivery device and the breathing mask device.—

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 12 includes the limitation of finding the gradient of the v° configuration, which is not described at any point in the specification, and is not a term commonly used by one of ordinary skill in the art. The claim will not be treated on the merits, since this limitation cannot be compared to anything.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11, 14, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 11, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For the purposes of examination, the claim will be treated as though directed to calculating the average gradient of unspecified intervals.

Regarding claim 14, the term "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For the purposes of examination, the claim will be treated as though calling for general trend analysis, with no parameters.

Regarding claim 16, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For the purposes of examination, the claim will be treated as though directed to calculating a differential over an unspecified interval.

Regarding claims 9 and 15, the term "the differential" renders the claim indefinite because it is not clear what is being compared or included in the comparison. The claims will not be treated further on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 8, 13, 14, 16, and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Axe (US Patent 6085747).

Regarding claims 1, 13, 14, and 24, Axe discloses a method of processing a signal related to a person's respiratory activity (column 2, lines 38-40) to control pressure regulation during administration of breathable gas at least periodically at a pressure above ambient pressure (column 2, lines 4-14, 29-37) comprising processing the signal to generate evaluation results that differentiate between obstructive and central breathing disorders (column 1, lines 49-51; column 2, lines 41-43; column 5 line 63 to column 6 line 13), and an apparatus for doing so (figure 1).

Regarding claims 5, 8, and 16, Axe further discloses repeatedly finding the first derivative of the signal representing respiratory flow – that is, the area under the signal's curve – to evaluate the patient's breathing disturbances (column 5, lines 56-58; column 8, lines 37-39; figure 14).

Regarding claim 25, Axe discloses an apparatus comprising a device for delivering a breathing gas to a patient (element 43) at various pressure levels including

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a pressure above ambient pressure (column 2, lines 49-55), a measuring device for generating a signal with respect to the flow of the breathing gas (elements 45, 48), a device for regulating the flow of the breathing gas to a predetermined reference pressure, a device for pre-setting the reference pressure (element 57), and a signal processing device configured to use variations in reference features specific to a respiratory cycle to indicate whether a current or impending breathing disorder is obstructive or central (column 1, lines 49-51; column 2, lines 41-43; column 5 line 63 to column 6 line 13), where the reference pressure is determined based on the indicated type of breathing disorder (figure 6).

Regarding claim 26, Axe further includes a breathing mask (element 39) and a respiratory gas line (element 41) between the delivery device (element 43) and the mask (figure 1).

Regarding claim 27, Axe discloses an apparatus for evaluation of measurement data containing information about a patient's breathing patterns (figures 2, 3, 6) comprising a signal processing device (element 57) that uses variations in features specific to respiratory cycle variations to generate results indicating whether the measurement data series contains sequences of obstructive or central breathing disorders (column 1, lines 49-51; column 2, lines 41-43; column 5 line 63 to column 6 line 13).

Regarding claim 28, Axe further discloses displaying the measurement data, including identifying the sequences of disturbed breathing (figures 2, 3, 6).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axe in view of Berthon-Jones (US Patent 6029665).

Regarding claim 10, Axe discloses all the elements of the claimed invention, as described above, except for monitoring the curve shape of an inspiratory cycle. Berthon-Jones teaches a method of respiratory monitoring that distinguishes between types of breathing disorders comprising monitoring the curve shape of an inspiratory cycle (column 10, lines 13-39), in order to determine the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Axe and monitored the shape of an inspiratory curve, as taught by Berthon-Jones, in order to determine the patient's condition.

Regarding claim 18, Axe discloses all the elements of the claimed invention, as described above, except for performing an evaluation of the nature and constitution of the patient's upper respiratory tracts. Berthon-Jones teaches a method of respiratory monitoring to distinguish between types of breathing disorders comprising monitoring the patency of the patient's upper respiratory tracts (column 3, lines 25-52; column 9, lines 54-57), in order to determine the origin of a respiratory disorder. It would have

been obvious to one of ordinary skill in the art at the time the invention was made to have followed Axe and monitored the condition of the patient's upper respiratory tracts, as taught by Berthon-Jones, in order to determine the origin of a respiratory disorder.

10. Claims 2-4, 6, 7, 11, 17, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axe in view of Rapoport (US Patent 5335654).

Regarding claims 2-4, 6, 7, 17, 21, and 22, Axe discloses all the elements of the claimed inventions, as described above, except for finding inspiratory and expiratory flow times, and using their ratio to determine the origin of a breathing disorder. Rapoport teaches a method of monitoring breathing to determine the origin of a breathing disorder comprising finding inspiratory and expiratory flow times and their ratio, and using that ratio to determine if a breathing disorder is obstructive (column 4, lines 25-45), in order to effectively treat the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of Axe and found and used an inspiratory/expiratory time ratio to determine the origin and characteristics of a breathing disorder, as taught by Rapoport.

Regarding claim 11, Axe discloses all the elements of the claimed invention, as disclosed above, except for finding the average gradient of the measurement signal. Rapoport teaches a method of monitoring breathing to determine the origin of a breathing disorder comprising finding the average gradient of a measured respiratory signal (column 5, lines 40-43), in order to effectively treat the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to

have followed the method of Axe and found the signal's average gradient, as taught by Rapoport, in order to effectively treat the patient.

Allowable Subject Matter

11. Claims 19, 20, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claim 19, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders, where the processing comprises analyzing the shape of the signal's curve to find the number of local maxima and minima, the amplitude of the local maxima and minima, the sequence of the magnitudes of the amplitudes of the local maxima and minima, and the frequency of the sequence of the local maxima and minima.

The prior art of record fails to anticipate or make obvious the invention of claim 20, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders, where the processing comprises spectral analysis and analysis of the amplitude of a snoring signal.

The prior art of record fails to anticipate or make obvious the method of claim 23, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders comprising performing an evaluation procedure that generates information about the nature of a patient's upper respiratory

tracts that differentiates between central and obstructive apneas, the elastic properties of the respiratory tracts, the location of an obstruction, the degree of severity of an apnea, and the patient's Pcrit (critical collapse pressure) value.

Berthon-Jones teaches determining upper airway patency; Madaus (US Patent 6530372) discloses determining a Pcrit value when delivering pressurized breathing gas; neither Berthon-Jones, Madaus, nor any of the other aforementioned references disclose monitoring the elastic properties of a patient's upper respiratory tracts.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publications 2003/0045806 to Brydon, 2002/0043264 to Wickham, 2006/0037615 to Wilkinson; US Patents 6814074 to Nadjafizadeh, 6651652 to Ward, 6739335 to Rapport, 5146918 to Kallok, and 6752151 to Hill, which disclose similar inventions.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735